510(k) Summary: 510(k) for the cobas c 501 ISE, Modified Calibration

K132418

DEC 18 2013

Introduction	The information in this 510(k) summary is being submitted in accordance with requirements of 21 CFR 807.92.
Submitter name, address, and contact	Contact Person: Khoa Tran Roche Diagnostics 9115 Hague Road Indianapolis, IN 46250 Phone: (317) -521-3409 Fax: (317) -521-2324 Email: khoa.tran@roche.com Date Prepared: October 17, 2013
Device name	Proprietary name: cobas c 501 ISE Indirect Na, K, Cl for Gen. 2. Common name: Sodium Test System Potassium Test System Chloride Test System Classification: Ion-Specific Electrode Sodium Ion-Specific Electrode Potassium Ion-Specific Electrode Chloride
Predicate Device	ISE Indirect Na, K, Cl for Gen.2 k053165
Establishment registration	For the cobas c 501 ISE module, the establishment registration number for Roche Diagnostics GmbH in Mannheim, Germany is 9610126. The establishment registration number for Roche Diagnostics, United States is 1823260.

Classification

The FDA has classified the Sodium, Potassium, and Chloride Test Systems as Class II devices.

Panel	Product Code	Classification Name	Regulation
Clinical Chemistry (75)	JGS	Ion Specific Electrode, Sodium	21 CFR 862.1665
Clinical Chemistry (75)	CEM	Ion Specific Electrode, Potassium	21 CFR 862.1600
Clinical Chemistry (75)	CGZ	Ion Specific Electrode, Chloride	21 CFR 862.1170

Proposed labeling

Draft labeling sufficient to describe the device, its intended use, and the directions for use on the **cobas c 501** analyzer module is included in the submission.

The ISE Gen 2 reagent was cleared in k053165 for application to the Roche/Hitachi family of analyzers.

Device description

The cobas 6000 analyzer series with an ISE module is an Ion-Selective Electrode (ISE) system for the determination of sodium, potassium, and chloride in serum, plasma, and urine. The cobas 6000 analyzer series, including the cobas c 501 with ISE for Serum, Plasma and Urine sample types was previously cleared in k060373. This premarket notification seeks to obtain FDA review and clearance for the cobas c 501 ISE, Modified Calibration for Serum, Plasma and Urine sample types.

An ISE makes use of the unique properties of certain membrane materials to develop an electrical potential (electromotive force, EMF) for the measurements of ions in solution. The electrode has a selective membrane in contact with both the test solution and an internal filling solution. The internal filling solution contains the test ion at a fixed concentration. Because of the particular nature of the membrane, the test ions will closely associate with the membrane on each side. The membrane EMF is determined by the difference in concentration of the test ion in the test solution and the internal filling solution. The EMF develops according to the Nernst equation for a specific ion in solution (see package insert for further explanation).

Aqueous ISE Standards Low and High were cleared in k053165. The modified calibration in this submission included the use of ISE Standards Low (S1) and High (S2) for 2-point calibration and the Standard High for compensation (S3). Previously, a serum-based ISE compensator was used for S3 compensation. The modification is switching from serum-based ISE compensator for S3 to ISE Standard High. In the new calibration scheme, the ISE Standard High will be used for both S2 and S3.

Intended use

The ISE module of the Roche/Hitachi **cobas c** systems is intended for the quantitative determination of sodium, potassium and chloride in serum, plasma or urine using ion-selective electrodes.

Indications for use	The ISE module of the Roche / Hitachi systems is intended for the quantitative determination of sodium, potassium, and chloride in serum, plasma, or urine using ion-selective electrodes. Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.
Substantial equivalence - comparison	The following table compares the cobas c 501 ISE Gen. 2, Modified Calibration for Serum, Plasma and Urine sample types to its predicate device, the cobas c 501 analyzer module with ISE Gen.2 reagent, originally cleared in k053165.

Comparison of Systems – similarities and differences

System Comparison		
Parameter	Predicate: cobas c 501 ISE Gen. 2 with serum-based ISE Compensator k053165	cobas c 501 ISE Gen. 2, Modified Calibration, with ISE Standard High (S3)
Intended use	The ISE module of the Roche/Hitachi **cobas c** system is intended for the quantitative determination of sodium, potassium and chloride in serum, plasma or urine using ion-selective electrodes.	Same
Measurement principle	ISE Potentiometry	Same
Reagent container	Plastic bottles closed via screw caps	Same
Onboard storage temperature	5-12 °C	Same
ISE Module	Integrated into cobas c 501 analyzer	Same
Ion Selective electrodes (ISEs)	Potentiometric chloride, potassium, sodium and reference electrodes	Same

Comparison of assays – similarities and differences

(Sodium)

Assay Comparison Sodium								
Parameter	Predicate: cobas c 501 ISE Gen. 2 with serum-based ISE Compensator				cobas c 501 ISE Gen. 2, Modified Calibration, with ISE Standard High			
Repeatability		Mean [mmol/L]	SD [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	124.8	0.36	0.3	Low	84.8	0.2	0.3
	High	144.9	0.43	0.3	Med	121.4	0.3	0.3
	PNU	124.9	0.38	0.3	MDL	131.6	0.3	0.2
	PPU	149.2	0.35	0.3	High	176.7	0.3	0.2
					PNU	126.0	0.2	0.2
					PPU	148.2	0.3	0.2
Intermediate precision (CLSI)		Mean [mmol/L]	SD [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	124.9	0.75	0.6	Low	84.8	1.0	1.1
	High	144.9	0.77	0.5	Med	121.4	0.8	0.6
	PNU	124.7	0.75	0.6	MDL	131.6	0.7	0.5
	PPU	149.9	0.80	0.5	High	176.7	0.6	0.4
					PNU	126.0	0.7	0.6
					PPU	148.2	0.5	0.4
Method Comparison to reference (Flame Photometer)	N = 51 (Plasma) Days = 3 Correlation = 0.993 Slope (Bablok) = 0.976 Intercept (Bablok) = +2.041 Range (X) = 132.7 – 164.1				N = 52 (Plasma) Days = 2 Correlation = 0.999 Slope (Bablok) = 1.000 Intercept (Bablok) = 0.200 Range (X) = 86.7 – 172 N = 51 (Serum) Days = 2 Correlation = 0.998 Slope (Bablok) = 0.992 Intercept (Bablok) = 1.633 Range (X) = 97.6 -178			
Method comparison to predicate	N = 51 (Plasma) Days = 3 Correlation = 0.998 Slope (Bablok) = 1.000 Intercept (Bablok) = -0.100 Range (X) = 131.2 -162.3				N = 52 (Plasma) Days = 2 Correlation = 1.000 Slope (Bablok) = 1.016 Intercept (Bablok) = -1.456 Range (X) = 87.6 – 170 N = 51 (Serum) Days = 2 Correlation = 0.999 Slope (Bablok) = 1.009 Intercept (Bablok) = -0.515 Range (X) = 97.3 -176			
Detection Limit	Not determined				LoB = 3.9 mmol/L LoD = 5.7 mmol/L LoQ = 11.1 mmol/L			
Reportable range	80 -180 mmol/L				80 – 180 mmol/L			

Comparison of assays – similarities and differences

(Sodium)

Assay Comparison Sodium - Urine								
Parameter	Predicate: cobas c 501 ISE Gen. 2 with serum-based ISE Compensator				cobas c 501 ISE Gen. 2, Modified Calibration, with ISE Standard High			
Repeatability		Mean [mmol/L]	SD [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	16.7	0.27	1.6	Low	30.6	0.1	0.2
	High	166.8	0.63	0.4	Med	131.7	0.2	0.2
	Liq 1	76.3	0.31	0.4	MDL	23.3	0.1	0.3
	Liq 2	175.5	0.47	0.3	High	236.7	0.4	0.2
					Liq 1	81.6	0.2	0.2
					Liq 2	172.3	0.2	0.1
Intermediate precision (CLSI)		Mean [mmol/L]	SD [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	15.5	0.62	4.0	Low	30.6	0.9	3.0
	High	166.7	0.87	0.5	Med	131.7	0.6	0.5
	Liq 1	75.7	0.75	1.0	MDL	23.3	0.9	3.8
	Liq 2	176.6	1.07	0.6	High	236.7	1.3	0.6
					Liq 1	81.6	1.3	1.6
					Liq 2	172.3	2.6	1.5
Method Comparison to reference (flame photometer)	N = 51 Days = 3 Correlation = 1.000 Slope (Bablok) = 1.001 Intercept (Bablok) = -1.263 Range (X) = 19.9 – 257.4				N = 100 Days = 2 Correlation = 1.000 Slope (Bablok) = 0.964 Intercept (Bablok) = 4.032 Range (X) = 23.5 – 249.8			
Method comparison to predicate	N = 51 Days = 3 Correlation = 1.000 Slope (Bablok) = 1.011 Intercept (Bablok) = -0.247 Range (X) = 17.9 -253.0				N = 100 Days = 2 Correlation = 1.000 Slope (Bablok) = 0.995 Intercept (Bablok) = 0.687 Range (X) = 25.1 – 245.4			
Detection Limit	Not determined				LoB = 3.9 mmol/L LoD = 5.7 mmol/L LoQ = 11.1 mmol/L			
Reportable range	10-250 mmol/L				20 - 250 mmol/L			
Extended Range	250-375 mmol/L (samples diluted via rerun function)				250 - 375 mmol/L (samples diluted via rerun function)			

Comparison of assays – similarities and differences, (Potassium)

Assay Comparison Potassium								
Parameter	Predicate: cobas c 501 ISE Gen. 2 with serum-based ISE Compensator				cobas c 501 ISE Gen. 2, Modified Calibration, with ISE Standard High			
Repeatability		Mean [mmol/L]	SD [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	4.68	0.03	0.5	Low	1.62	0.01	0.7
	High	8.62	0.04	0.5	Med	4.97	0.04	0.7
	PNU	3.37	0.02	0.5	MDL	2.63	0.02	0.6
	PPU	6.06	0.03	0.5	High	9.46	0.06	0.6
					PNU	3.57	0.03	0.8
					PPU	6.59	0.04	0.6
Intermediate precision (CLSI)		Mean [mmol/L]	SD [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	4.72	0.03	0.7	Low	1.62	0.03	1.6
	High	8.63	0.04	0.5	Med	4.97	0.04	0.8
	PNU	3.39	0.02	0.5	MDL	2.63	0.03	1.0
	PPU	6.08	0.03	0.6	High	9.46	0.07	0.7
					PNU	3.57	0.04	1.0
					PPU	6.59	0.05	0.7
Method Comparison to reference (Flame Photometry)	N = 51 (Plasma) Days = 3 Correlation = 0.998 Slope (Bablok) = 0.983 Intercept (Bablok) = -0.026 Range (X) = 3.23 – 6.35				N = 52 (Plasma) Days = 2 Correlation = 1.000 Slope (Bablok) = 1.010 Intercept (Bablok) = - 0.022 Range (X) = 2.1 – 9.19 N = 54 (Serum) Days = 2 Correlation = 1.000 Slope (Bablok) = 1.005 Intercept (Bablok) = -0.020 Range (X) = 1.59 – 9.56			
Method comparison to predicate	N = 51 (Plasma) Days = 3 Correlation = 0.998 Slope (Bablok) = 0.988 Intercept (Bablok) = 0.052 Range (X) = 3.14 – 6.26				N = 52 (Plasma) Days = 2 Correlation = 1.000 Slope (Bablok) = 1.008 Intercept (Bablok) = 0.018 Range (X) = 2.02 -9.13 N = 54 (Serum) Days = 2 Correlation = 1.000 Slope (Bablok) = 1.004 Intercept (Bablok) = 0.302 Range (X) = 1.52 – 9.45			
Detection Limit	Not determined				LoB = 0.17 mmol/L LoD = 0.24 mmol/L LoQ = 0.41 mmol/L			
Reportable range	1.5-10.0 mmol/L				1.5 – 10.0 mmol/L			

Comparison of assays – similarities and differences, (Potassium)

Assay Comparison Potassium - Urine								
Parameter	Predicate: cobas c 501 ISE Gen. 2 with serum-based ISE Compensator				cobas c 501 ISE Gen. 2, Modified Calibration, with ISE Standard High			
Repeatability		Mean [mmol/L]	SD [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	8.79	0.04	0.4	Low	5.15	0.03	0.6
	High	72.04	0.53	0.7	Med	52.08	0.32	0.6
	Liq 1	31.13	0.21	0.7	MDL	15.39	0.09	0.6
	Liq 2	68.76	0.36	0.5	High	90.34	0.67	0.7
					Liq 1	31.48	0.19	0.6
					Liq 2	70.56	0.43	0.6
Intermediate precision (CLSI)		Mean [mmol/L]	SD [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	8.99	0.04	0.4	Low	5.15	0.04	0.7
	High	72.04	0.53	0.7	Med	52.08	0.67	1.3
	Liq 1	31.13	0.21	0.7	MDL	15.39	0.14	0.9
	Liq 2	68.76	0.36	0.5	High	90.34	1.38	1.5
					Liq 1	31.48	0.53	1.7
					Liq 2	70.56	1.17	1.7
Method Comparison to reference (Flame Photometry)	N = 51 Days = 3 Correlation = 1.000 Slope (Bablok) = 1.033 Intercept (Bablok) = -0.023 Range (X) = 9.20 – 95.10				N = 105 Days = 2 Correlation = 1.000 Slope (Bablok) = 1.018 Intercept (Bablok) = 0.397 Range (X) = 4.00 – 97.20			
Method comparison to predicate	N = 51 Days = 3 Correlation = 0.999 Slope (Bablok) = 0.982 Intercept (Bablok) = 0.323 Range (X) = 9.68 – 98.55				N = 105 Days = 2 Correlation = 0.999 Slope (Bablok) = 0.997 Intercept (Bablok) = 0.062 Range (X) = 4.05 – 97.35			
Detection Limit	Not determined				LoB = 0.17 mmol/L LoD = 0.24 mmol/L LoQ = 0.41 mmol/L			
Reportable range	1 -100 mmol/L				3 – 100 mmol/L			
Extended Range	100-150 mmol/L (samples diluted via rerun function)				100 -150 mmol/L (samples diluted via rerun function)			

Comparison of assays – similarities and differences, (Chloride)

Assay Comparison Chloride								
Parameter	Predicate: cobas c 501 ISE Gen. 2 with serum-based ISE Compensator				cobas c 501 ISE Gen. 2, Modified Calibration, with ISE Standard High			
Repeatability		Mean [mmol/L]	SD [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	86.6	0.30	0.3	Low	68.5	0.2	0.3
	High	118.4	0.38	0.3	Med	129.0	0.4	0.3
	PNU	82.1	0.41	0.5	MDL	92.3	0.2	0.3
	PPU	114.7	0.31	0.3	High	139.0	0.3	0.2
					PNU	86.2	0.2	0.3
					PPU	119.2	0.3	0.2
Intermediate precision (CLSI)		Mean [mmol/L]	SD [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	88.2	0.55	0.6	Low	68.5	0.6	0.8
	High	118.4	0.61	0.5	Med	129.0	0.6	0.5
	PNU	81.9	0.36	0.4	MDL	92.3	0.5	0.6
	PPU	115.4	0.62	0.5	High	139.0	0.6	0.4
					PNU	86.2	0.5	0.6
					PPU	119.2	0.5	0.4
Method Comparison to reference (Coulometry)	N = 51 (Plasma) Days = 3 Correlation = 0.995 Slope (Bablok) = 0.954 Intercept (Bablok) = +1.438 Range (X) = 92.0 – 132.0				N = 52 (Plasma) Days = 2 Correlation = 0.998 Slope (Bablok) = 1.023 Intercept (Bablok) = -0.769 Range (X) = 69.0 - 133 N = 53 (Serum) Days = 2 Correlation = 0.999 Slope (Bablok) = 1.043 Intercept (Bablok) = -2.843 Range (X) = 62.0 – 136			
Method comparison to predicate	N = 51 (Plasma) Days = 3 Correlation = 0.999 Slope (Bablok) = 0.978 Intercept (Bablok) = +1.744 Range (X) = 90.7 – 128.9				N = 52 (Plasma) Days = 2 Correlation = 0.999 Slope (Bablok) = 1.006 Intercept (Bablok) = -0.118 Range (X) = 69.4 – 134 N = 53 (Serum) Days = 2 Correlation = 1.000 Slope (Bablok) = 0.997 Intercept (Bablok) = 0.872 Range (X) = 61.4 - 138			
Detection Limit	Not determined				LoB = 3.40 mmol/L LoD = 4.7 mmol/L LoQ = 5.5 mmol/L			
Reportable range	60 - 140 mmol/L				60 - 140 mmol/L			

Comparison of assays – similarities and differences, (Chloride)

Assay Comparison Chloride - Urine								
Parameter	Predicate: cobas c 501 ISE Gen. 2 with serum-based ISE Compensator				cobas c 501 ISE Gen. 2, Modified Calibration, with ISE Standard High			
Repeatability		Mean [mmol/L]	SD [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	20.4	0.29	1.4	Low	25.8	0.1	0.2
	High	165.0	0.81	0.5	Med	131.4	0.3	0.2
	Liq 1	101.9	0.43	0.4	MDL	24.3	0.1	0.3
	Liq 2	203.0	0.54	0.3	High	243.4	0.6	0.2
					Liq 1	97.5	0.2	0.2
					Liq 2	198.2	0.4	0.2
Intermediate precision (CLSI)		Mean [mmol/L]	SD [mmol/L]	CV [%]		Mean [mmol/L]	SD [mmol/L]	CV [%]
	Low	19.9	0.55	2.8	Low	25.8	0.6	2.3
	High	165.4	1.17	0.7	Med	131.4	0.7	0.5
	Liq 1	101.5	0.34	0.3	MDL	24.3	0.6	2.4
	Liq 2	206.1	1.26	0.6	High	243.4	1.8	0.7
					Liq 1	97.5	1.6	1.6
					Liq 2	198.2	2.3	1.2
Method Comparison to reference (Coulometry)	N = 51 Days = 3 Correlation = 1.000 Slope (Bablok) = 1.002 Intercept (Bablok) = -2.739 Range (X) = 21.0 – 274.0				N = 105 Days = 2 Correlation = 0.998 Slope (Bablok) = 1.020 Intercept (Bablok) = -1.700 Range (X) = 22.0 - 248.0			
Method comparison to predicate	N = 51 Days = 3 Correlation = 1.000 Slope (Bablok) = 1.009 Intercept (Bablok) = -1.715 Range (X) = 18.5 – 269.0				N = 105 Days = 2 Correlation = 1.000 Slope (Bablok) = 0.989 Intercept (Bablok) = 0.669 Range (X) = 21.2 – 249.9			
Detection Limit	Not determined				LoB = 3.4 mmol/L LoD = 4.7 mmol/L LoQ = 5.5 mmol/L			
Reportable range	10 -250 mmol/L				20 - 250 mmol/L			
Extended Range	250 - 375 mmol/L (samples diluted via rerun function)				250 – 375 mmol/L (samples diluted via rerun function)			

Conclusion:

The data presented in this premarket notification demonstrates cobas c 501 ISE Gen. 2 assay with the modified calibration performs substantially equivalent to the predicate device, the cobas c 501 ISE Gen. 2 with the original calibration (k053165).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2013

ROCHE DIAGNOSTICS
KHOA TRAN
REGULATORY AFFAIRS CONSULTANT
9115 HAGUE ROAD
INDIANAPOLIS IN 46250

Re: K132418
Trade/Device Name: cobas c 501 ISE Indirect Na, K, Cl for Gen. 2
Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium test system
Regulatory Class: II
Product Code: JGS, CEM, CGZ
Dated: December 12, 2013
Received: December 13, 2013

Dear Mr. Tran:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

k132418

Device Name

cobas c 501 ISE Indirect Na, K, Cl for Gen. 2

Indications for Use *(Describe)*

The ISE module of the Roche / Hitachi systems is intended for the quantitative determination of sodium, potassium, and chloride in serum, plasma, or urine using ion-selective electrodes.

Sodium measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance. Potassium measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels. Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung W. Chan -S